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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,638	04/26/2001	Scott J. Davis	P-9596.00	9208

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EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	7

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/843,638	DAVIS ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *20-23,26,29,30,35 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,24,25,27,28,31-34,36-42,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 4*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 8-19, 25, 27-28, 31-34, 36-37, 40-42, 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Romkee (5,603,730).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 1, 10, 13, and 31, Romkee shows a implantable therapy delivery device; a therapy delivery element (14); an adjustable anchor (24) coupleable to the therapy delivery element, the adjustable anchor being implantable and including a therapy grip element (50) configured to be actuated to an open position and a closed position, at least two extension elements (32, 34) connected to the therapy grip element extending perpendicularly from the therapy delivery element and configured to actuate the therapy grip element, and a tissue fixation element (86, 88) connected to the extension elements and configured to be fixed to a tissue location from an axial direction to the therapy delivery element (Col. 2, line 65-Col. 3, line 1).

Regarding claims 2, 11, 14, 32, 36, and 44, Romkee shows the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue (Col. 3, lines 32-35, Fig. 1).

With respect to claims 3, 12, 15, 33, 37, and 45, Romkee shows the two extension elements (32, 34) are actuated with a single pincer motion (Fig. 5).

Regarding claims 4-5, and 40-41, Romkee shows the therapy delivery system is an electrical lead and a catheter.

With respect to claim 16, Romkee shows the therapy grip element has a substantially rigid grip surface.

Regarding claim 17, Romkee shows the therapy grip element is configured in a normally closed position (Col. 2, line 65-Col. 3, line 24).

With respect to claims 18-19, Romkee shows the therapy grip element (50) covers at least about 25 and 270 degrees of the therapy delivery element (Fig. 3).

Regarding claim 25, Romkee shows the extension element is positioned at less than about 180 degrees in relation to the therapy delivery element (Figs. 3, 5).

With respect to claim 27, Romkee shows the tissue fixation element (86, 88) has a suture fixation configuration (Col. 2, lines 59-60).

Regarding claim 28, Romkee shows the tissue fixation element is configured at a predetermined position in relation to the extension element (Fig. 2).

With respect to claims 34, and 42, Romkee shows a method comprising inserting the therapy delivery element into a human body, opening the therapy grip element by actuating the extension elements, placing the therapy grip element on the therapy delivery element, positioning the therapy grip element at a grip location on the therapy delivery element, closing the therapy grip element by actuating the extension elements, securing the therapy grip element on the therapy delivery device when the therapy grip element is closed, positioning a tissue fixation element at a tissue location, and fixing the tissue fixation element to the tissue at the tissue

location in an orientation along the axial length of the therapy delivery element, and connecting the therapy delivery element to the therapy delivery device (Col. 3, lines 10-47).

3. Claims 1, 4-5, 8-10, 18-19, 24-25, 27-28, 31, 34, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kristiansen (5,242,431).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 1, 10, 13, and 31, Kristiansen shows a implantable therapy delivery device; a therapy delivery element (12); an adjustable anchor (10) coupleable to the therapy delivery element, the adjustable anchor being implantable and including a therapy grip element (32) configured to be actuated to an open position and a closed position, at least two extension elements (two extensions 54, 56, on element 50) connected to the therapy grip element extending perpendicularly from the therapy delivery element and configured to actuate the therapy grip element, and a tissue fixation element (62) connected to the extension elements and configured to be fixed to a tissue location from an axial direction to the therapy delivery element (Fig. 4).

Regarding claims 4-5, and 40-41, Kristiansen shows the therapy delivery system is an electrical lead and a catheter.

With respect to claims 18-19, Kristiansen shows the therapy grip element (50) covers at least about 25 and 270 degrees of the therapy delivery element (Figs. 2-3).

Regarding claim 24, Kristiansen shows the therapy grip element has a grip stop surface (36, 44, 46) that engages a complimentary extension stop surface (54, 56) to prevent the extension element from actuating the therapy grip element beyond a desired actuation limit

Regarding claim 25, Kristiansen shows the extension element (54, 56) is positioned at less than about 180 degrees in relation to the therapy delivery element (Fig. 1).

With respect to claim 27, Kristiansen shows the tissue fixation element (62) has a suture fixation configuration (Col. 4, lines 29- 32).

Regarding claim 28, Kristiansen shows the tissue fixation element is configured at a predetermined position in relation to the extension element (Fig. 1).

With respect to claims 34, and 42, Kristiansen shows a method comprising inserting the therapy delivery element into a human body, opening the therapy grip element by actuating the extension elements, placing the therapy grip element on the therapy delivery element, positioning the therapy grip element at a grip location on the therapy delivery element, closing the therapy grip element by actuating the extension elements, securing the therapy grip element on the therapy delivery device when the therapy grip element is closed, positioning a tissue fixation element at a tissue location, and fixing the tissue fixation element to the tissue at the tissue location in an orientation along the axial length of the therapy delivery element, and connecting the therapy delivery element to the therapy delivery device (Col. 5, lines 3-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6-7, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romkee (5,603,730). Romkee discloses the claimed invention except for the implantable

therapy delivery device being a neurostimulator or therapeutic substance delivery device. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the implantable therapy delivery device as taught by Romkee with a neurostimulator or therapeutic substance delivery device, since applicant has not disclosed that this particular implantable therapy delivery device provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any implantable therapy delivery device such as the defibrillator taught by Romkee for defibrillating the heart.

6. Claims 6-7, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kristiansen (5,242,431). Kristiansen discloses the claimed invention except for the implantable therapy delivery device being a neurostimulator or therapeutic substance delivery device. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the implantable therapy delivery device as taught by Kristiansen with a neurostimulator or therapeutic substance delivery device, since applicant has not disclosed that this particular implantable therapy delivery device provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any implantable therapy delivery device such as the pacemaker taught by Kristiansen for pacing the heart.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Werner et al (5,931,861) shows an anchor device with two extension members and a gripping element (Figs. 14-18). Wolosszko shows neurostimulation leads with an anchor element.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

Angela D. Sykes

kld

ANGELA D. SYKES
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